

Complete if Known

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

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of

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Application Number	10/623,431
Filing Date	July 18, 2003
First Named Inventor	Jay D. KRANZLER et al.
Art Unit	1614
Examiner Name	Alicia R. HUGHES
Attorney Docket Number	11013.0012-00000

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS

Examiner Initials	Cite No. ¹	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		US-4,956,388	09-11-1990	Robertson et al.	
		US-5,744,474	04-28-1998	Thor	
		US-5,792,796	08-11-1998	Woodruff et al.	
		US-5,942,549	08-24-1999	Vargas	
		US-5,945,416	08-31-1999	Shannon et al.	
		US-6,028,070	02-22-2000	Heiligenstein	
		US-6,184,222	02-06-2001	Heiligenstein	
		US-6,451,788	09-17-2002	Horrobin et al.	
		US-6,489,341	12-03-2002	Jerussi	
		US-6,596,900	07-22-2003	Blakemore et al.	
		US-6,602,911	08-25-2003	Kranzler et al.	
		US-6,635,675	10-21-2003	Kranzler et al.	
		US-6,992,110	01-31-2006	Kranzler et al.	
		US-2001-0036943	11-01-2001	Coe et al.	
		US-2002-0006963	01-17-2002	Young et al.	
		US-2002-0086864	07-04-2002	Wong et al.	
		US-2002-0094986	07-18-2002	Chappell et al.	
		US-2002-0147196	10-10-2002	Quessy et al.	
		US-2002-0156067	10-24-2002	Wong et al.	
		US-2002-0187958	12-12-2002	Horrobin et al.	
		US-2003-0013689	01-16-2003	Helton et al.	
		US-2003-0130353	07-10-2003	Kranzler et al.	
		US-2003-0143548	07-31-2003	Camilleri et al.	
		US-2003-0203055	10-30-2003	Rao et al.	
		US-2003-0232805	12-18-2003	Kranzler et al.	
		US-2004-0014739	01-22-2004	Koppel	
		US-2004-0019116	01-29-2004	Kranzler et al.	
		US-2004-0106681	06-03-2004	Rao et al.	
		US-2004-0132826	07-08-2004	Hirsh et al.	
		US-2004-0228830	11-18-2004	Hirsh et al.	
		US-2004-0229956	11-18-2004	Kranzler et al.	
		US-2005-0096395	05-05-2005	Rao et al.	
		US-2005-0014843	01-20-05	Allen et al.	
		US-2006-0024366	02-02-2006	Hirsh et al.	

IDS Form PTO/SB/08: Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
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				Examiner Name	Alicia R. HUGHES
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U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS					
		US-2007-0072946	03-29-2007	Rao et al.	

Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
		GB 2 362 826 A	12-05-2001	Eli Lilly and Company Limited		
		WO 94/00114 A1	01-06-1994	Sepracor Inc.		
		WO 99/15176	04-01-1999	Eli Lilly and Company Limited		
		WO 03/039598 A1	05-15-2003	Cypress Bioscience, Inc.		
		WO 03/068211 A1	08-21-2003	Cypress Bioscience, Inc.		
		WO 2004/045718 A2	06-03-2004	Cypress Bioscience, Inc.		

NONPATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation ⁶	
	-	Chart of Cypress Bioscience applications related to milnacipran for treatment of various disorders.		
	-	AARON et al., "Overlapping conditions among patients with chronic fatigue syndrome, fibromyalgia, and temporomandibular disorder," <i>Arch. Intern. Med.</i> , 160: 221-227 (2000).		
	-	ALAGIRI et al., "Interstitial cystitis: unexplained associations with other chronic disease and pain syndromes," <i>Urology</i> , 49(Suppl. 5A): 52-57 (1997).		
	-	ANDERBERG et al., "Citalopram in patients with fibromyalgia - a randomized, double-blind, placebo-controlled study," <i>Eur. J. Pain</i> , 4: 27-35 (2000).		
	-	ANSARI, "The efficacy of newer antidepressants in the treatment of chronic pain: a review of current literature," <i>Harv. Rev. Psychiatry</i> , 7: 257-277 (2000).		
	-	ATKINSON et al., "Effects of noradrenergic and serotonergic antidepressants on chronic low back pain intensity," <i>Pain</i> , 83: 137-145 (1999).		
	-	BARKIN, "The management challenges of chronic pain: the roll of antidepressants," <i>Am. J. Ther.</i> , 7: 31-47 (2000).		
	-	BENNETT, "Pharmacological treatment of fibromyalgia," <i>J. Functional Syndromes</i> , 1: 79-92 (2001).		
	-	BUSKILA, "Drug therapy," <i>Baillieres Best Pract. Res. Clin. Rheumatol.</i> , 13: 479-485 (1999).		
	-	CACCIA, "Metabolism of the newer antidepressants: an overview of the pharmacological and pharmacokinetic implications," <i>Clin. Pharmacokinet.</i> , 34: 281-302 (1998).		
	-	CARETTE et al., "Comparison of amitriptyline, cyclobenzaprine, and placebo in the treatment of fibromyalgia. A randomized, double-blind clinical trial," <i>Arthritis Rheum.</i> , 37: 32-40 (1994).		
	-	CLAUW, "The pathogenesis of chronic pain and fatigue syndromes, with special reference to fibromyalgia," <i>Med. Hypotheses</i> , 44: 369-378 (1995).		
	-	CLAUW et al., "Chronic Pain and Fatigue Syndromes: Overlapping Clinical and Neuroendocrind Features and Potential Pathogenic Mechanisms," <i>Neuroimmunomodulation</i> , 4:134-153 (1997).		
	-	DWORKIN et al., "Clinical aspects of depression in chronic pain patients," <i>Clin. J. Pain</i> , 7: 79-94 (1991).		
	-	EISEN, "Venlafaxine therapy for vulvodynia," <i>The Pain Clinic</i> , 8: 365-367 (1995).		
	-	FARTHING, "Irritable bowel syndrome: new pharmaceutical approaches to treatment," <i>Baillieres Best Pract. Res. Clin. Gastroenterol.</i> , 13: 461-471 (1999).		

IDS Form PTO/SB/08: Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
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				Examiner Name	Alicia R. HUGHES
Sheet	3	of	5	Attorney Docket Number	11013.0012-00000

NONPATENT LITERATURE DOCUMENTS			
		FISHBAIN, "Evidence-based data on pain relief with antidepressants," <i>Ann. Med.</i> , 32: 305-316 (2000).	
		GIAMBERARDINO, "Recent and forgotten aspects of visceral pain," <i>Eur. J. Pain</i> , 3: 7-92 (1999).	
		GOLDENBERG et al., "A randomized, controlled trial of amitriptyline and naproxen in the treatment of patients with fibromyalgia," <i>Arthritis Rheum.</i> , 29: 1371-1377 (1986).	
		GOLDENBERG et al., "A randomized, double-blind crossover trial of fluoxetine and amitriptyline in the treatment of fibromyalgia," <i>Arthritis Rheum.</i> , 39: 1852-1859 (1996).	
		GRUBER et al., "The management of treatment-resistant depression in disorders on the interface of psychiatry and medicine," <i>The Psychiatric Clinics of North America</i> , 19: 351-369 (1996).	
		HANNONEN et al., "A randomized, double-blind, placebo-controlled study of miltiramine and amitriptyline in the treatment of fibromyalgia in females without psychiatric disorder," <i>Br. J. Rheumatol.</i> , 37: 1279-1286 (1998).	
		JAIN, "Addressing both the emotional and physical symptoms in depression," <i>Medscape CME program</i> (2003).	
		JUNG et al., "The efficacy of selective Serotonin reuptake inhibitors for the management of chronic pain," <i>J. Gen. Intern. Med.</i> , 12: 384-389 (1997).	
		KENT, "SNRIs, NaSSAs, and NaRIs: new agents for the treatment of depression," <i>Lancet</i> , 355: 911-918 (2000).	
		KRANZLER et al., "The psychopharmacology of fibromyalgia: a drug development perspective," <i>Psychopharmacol Bull.</i> , 36: 165-213 (2002).	
		LAUTENSCHLAGER, "Present state of medication therapy in fibromyalgia syndrome," <i>Scand. J. Rheumatol. Suppl.</i> , 113: 32-36 (2000).	
		LEVENTHAL, "Management of fibromyalgia," <i>Ann. Intern. Med.</i> , 131: 850-858 (1999).	
		MARTINDALE, <i>Antidepressants</i> , Pharmaceutical Press, London, 32 nd ed., pp. 271, 284, 298, 1485 (1999).	
		MAX et al., "Effects of desipramine, amitriptyline, and fluoxetine on pain diabetic neuropathy," <i>N. Engl. J. Med.</i> , 326: 1250-1256 (1992).	
		MONTGOMERY, "Venlafaxine: a new dimension in antidepressant pharmacotherapy," <i>J. Clin. Psychiatry</i> , 54: 119-126 (1993).	
		NICOLODI et al., "Fibromyalgia and headache. Failure of serotonergic analgesia and N-methyl-D-aspartate-mediated neuronal plasticity: their common clues," <i>Cephalalgia</i> , Suppl.21: 41-44 (1998).	
		NORREGAARD et al., "A randomized controlled trial of citalopram in the treatment of fibromyalgia," <i>Pain</i> , 61: 445-449 (1995).	
		NOVICK et al., "A randomized, double-blind, placebo-controlled trial of tegaserod in female patients suffering from irritable bowel syndrome with constipation," <i>Aliment Pharmacol. Ther.</i> , 16: 1877-1888 (2002).	
		PANDE et al., "Three randomised, placebo-controlled, double-blind trials of pregabalin treatment of generalized anxiety disorder (GAD)," 10(Suppl. 3): 344 Abstract (2000).	
		PEGHINI et al., "Imipramine decreases oesophageal pain perception in human male volunteers," <i>Gut</i> , 42: 807-813 (1998).	
		PUECH et al., "Milnacipran, a new serotonin and noradrenaline reuptake inhibitor: an overview of its antidepressant activity and clinical tolerability," <i>Int. J. Psychopharm.</i> , 12: 99-108 (1997).	
		QUIJADA-CARRERA et al., "Comparison of tenoxicam and bromazepam in the treatment of fibromyalgia: a randomized, double-blind, placebo-controlled trial," <i>Pain</i> , 65: 221-225 (1996).	
		RAO et al., "Pharmacological therapies in fibromyalgia," <i>Best Pract. Res. Clin. Rheumatol.</i> , 17: 611-627 (2003).	
		RENERIC et al., "Antidepressant behavioral effects by dual inhibition of monoamine reuptake in the rat forced swimming test," <i>Psychopharmacology</i> , 136: 190-197 (1998).	
		RUOFF, "Depression in the patient with chronic pain," <i>The Journal of Family Practice</i> , 43: S25-S33 (1996).	
		SAPER et al., "Nefazodone for chronic daily headache prophylaxis: an open-label study," <i>Headache</i> , 41: 465-474 (2001).	
		SHUTO et al., "Synthesis of (+) and (-) milnaciprans and their conformationally restricted analogs," <i>Tetrahedron Lett.</i> , 37: 641-644 (1996).	
		SINDRUP et al., "Efficacy of pharmacological treatment of neuropathic pain: an update and effect related to mechanism of drug action," <i>Pain</i> , 83: 389-400 (1999).	
		SWAYNOK et al., "Peripheral antinociceptive actions of desipramine and fluoxetine in an inflammatory and neuropathic pain test in the rat," <i>Pain</i> , 82: 149-158 (1999).	

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Sheet	4	of	5	Application Number	10/623,431
				Filing Date	July 18, 2003
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NONPATENT LITERATURE DOCUMENTS

	THEMA, "The drug induced alleviation of carcinoma pain," <i>Much. Med. Wochenschr.</i> , 124:855-856 (1982).	Abstract
	VAISHNAVI et al., "Milnacipran: A comparative analysis of human monoamine uptake and transporter binding affinity," <i>Biol Psychiatry</i> , 55: 320-322 (2004).	
	VITTON et al., "A double-blind placebo-controlled trial of milnacipran in the treatment of fibromyalgia," <i>Hum Psychopharmacol Clin Exp</i> , 19: S27-S35 (2004).	
	WATSON et al., "Amitriptyline versus maprotiline in postherpetic neuralgia: a randomized, double-blind, crossover trial," <i>Pain</i> , 48: 29-36 (1992).	
	WESSELMAN, "Interstitial cystitis: A chronic visceral pain syndrome," <i>Urology</i> , 57(Suppl. 64): 32-39 (2001).	
	WESSELY et al., "Functional somatic syndromes: one or many?," <i>Lancet</i> , 354: 936-939 (1999).	
	WOLFE et al., "A double-blind placebo controlled trial of fluoxetine in fibromyalgia," <i>Scand. J. Rheum.</i> , 23: 255-259 (1994).	
	WOOLF et al., "Neuropathic pain: aetiology, symptoms, mechanisms, and management," <i>Lancet</i> , 353: 1959-1964 (1999).	
	YUNUS et al., "Towards a model of pathophysiology of fibromyalgia: aberrant central pain mechanisms with peripheral modulation," <i>J. Rheumatol.</i> , 19: 846-850 (1992).	
	Restriction Requirement dated October 20, 2006, in U.S. Application No. 10/678,767, filed October 3, 2003.	
	Response to Restriction Requirement dated November 16, 2006, in U.S. Application No. 10/678,767, filed October 3, 2003.	
	Office Action dated February 20, 2007, in U.S. Application No. 10/678,767, filed October 3, 2003.	
	Response to Office Action Under 37 C.F.R. 1.111 dated June 7, 2007, in U.S. Application No. 10/678,767, filed October 3, 2003.	
	Office Action dated August 27, 2007, in U.S. Application No. 10/678,767, filed October 3, 2003.	
	Response to Office Action Under 37 C.F.R. 1.111 dated November 27, 2007, in U.S. Application No. 10/678,767, filed October 3, 2003.	
	Final Office Action dated February 25, 2008, in U.S. Application No. 10/678,767, filed October 3, 2003.	
	Response to Final Office Action Under 37 C.F.R. 1.116 dated April 15, 2008, in U.S. Application No. 10/678,767, filed October 3, 2003.	
	Advisory Action dated May 12, 2008, in U.S. Application No. 10/678,767, filed October 3, 2003.	
	Office Action dated August 22, 2008, in U.S. Application No. 10/678,767, filed October 3, 2003.	
	Response to Office Action Under 37 C.F.R. 1.111 dated November 24, 2008, in U.S. Application No. 10/678,767, filed October 3, 2003.	
	Final Office Action dated March 4, 2009, in U.S. Application No. 10/678,767, filed October 3, 2003.	
	Office Action dated September 27, 2007, in U.S. Application No. 11/752,213, filed May 22, 2007.	
	Response to Office Action dated December 27, 2007, in U.S. Application No. 11/752,213, filed May 22, 2007.	
	Interview Summary dated January 10, 2008, in U.S. Application No. 11/752,213, filed May 22, 2007.	
	Restriction Requirement dated February 4, 2008, in U.S. Application No. 11/752,213, filed May 22, 2007.	
	Response to Restriction Requirement dated March 4, 2008, in U.S. Application No. 11/752,213, filed May 22, 2007.	
	Office Action dated August 12, 2008, in U.S. Application No. 11/752,213, filed May 22, 2007.	
	Response to Office Action dated December 12, 2008, in U.S. Application No. 11/752,213, filed May 22, 2007.	
	Final Office Action dated April 17, 2009, in U.S. Application No. 11/752,213, filed May 22, 2007.	
	Applicant Statement of Interview Summary dated May 7, 2009, in U.S. Application No. 11/752,213, filed May 22, 2007.	
	Amendment and Response to Office Action dated June 17, 2009, in U.S. Application No. 11/752,213, filed May 22, 2007.	
	Office Action dated September 18, 2008, in U.S. Patent Application No. 11/835,590, filed August 8, 2007.	

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		<i>Attorney Docket Number</i>	11013.0012-00000
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NONPATENT LITERATURE DOCUMENTS			
		Amendment and Response dated March 18, 2009, in U.S. Patent Application No. 11/835,590, filed August 8, 2007.	
	✓	Final Office Action dated June 4, 2009, in U.S. Patent Application No. 11/835,590, filed August 8, 2007.	
		Office Action dated October 7, 2008, in U.S. Application No. 11/835,620, filed August 8, 2007.	
		Amendment and Response filed April 6, 2009, in U.S. Application No. 11/835,620, filed August 8, 2007.	
		Office Action dated September 22, 2008, in U.S. Patent Application No. 12/035,820, filed February 22, 2008.	
		Amendment and Response to Office Action dated October 21, 2008, in U.S. Patent Application No. 12/035,820, filed February 22, 2008.	
		Restriction Requirement dated February 4, 2009, in U.S. Patent Application No. 12/035,820, filed February 22, 2008.	
		Amendment and Response to Restriction Requirement and Applicant Statement of Interview Summary dated June 17, 2009, in U.S. Patent Application No. 12/035,820, filed February 22, 2008.	
		First Examination Report for Indian Application No. 496/DELNP/2005, dated June 15, 2006.	
		Communication pursuant to Article 96(2) EPC dated October 25, 2006, in European Application No. 03748971.3	
		PCT International Preliminary Examination Report dated February 5, 2004, in International Application No. PCT/US02/35396	
		Amendment dated May 7, 2004, in European Application No. 02793880.2.	
		Communication pursuant to Article 96(2) EPC dated June 1, 2005, in European Application No. 02793880.2.	
		Response with amended claims dated November 24, 2005, in European Application No. 02793880.2.	
		Communication pursuant to Article 94(3) EPC dated December 17, 2007, in European Application No. 02793880.2.	
		Response with amended claims dated June 17, 2008, in European Application No. 02793880.2.	
		Examiner's first report dated March 5, 2008 in Australian Application No. 2003284005.	

Examiner Signature		Date Considered	
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.